

## **II. REMARKS**

### **A. Status of the Claims**

Claims 3, 6, 16, 17, 19, 20, 22-25 and 27-35 are pending. Independent claim 19 has been amended to correct a typographical error. It is respectfully submitted that no new matter has been added by virtue of this amendment.

### **B. Rejection under 35 U.S.C. § 103(a)**

In the Office Action, the Examiner rejected Claims 3, 6, 16, 17, 19, 20, 22-25, 27-33, 34 and 35 under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of 6,253,920 B1 to Kallgren (hereinafter “Kallgren”); U.S. Patent No. 6,365,184 to Depui et al. (hereinafter “Depui et al.”); and WO 88/02342 to Eek (hereinafter “Eek”).

In making the rejections, the Examiner stated that “[i]t is the position of the examiner that one of ordinary skill would be motivated to combine the disclosures of Kallgren, Depui et al., and Eek in order to create a packaging system comprising a proton pump inhibitor in combination with a non-steroidal anti-inflammatory drug.” The Examiner further stated that “[i]t is the position of the examiner that one of ordinary skill in the art would recognize that the aims of the Kallgren, Depui et al., and Eek are similar in the area of improving patient compliance,” and “[a]s the disclosed invention of Kallgren is not limited to any particular types of drugs to be packaged, one of ordinary skill can expect to create a drug pack comprising dosages of lansoprazole and naproxen in accordance with a combination dosage regimen with a reasonable expectation of success.”

This rejection is traversed. The Office Action relies on Kallgren to teach a blister package for packaging drugs that should be administered in combination. However, it is respectfully submitted that the Kallgren reference does not teach or suggest the claimed

invention because it does not provide for the specific active ingredients in separate dosage forms in accordance with the currently pending claims. It is expressly admitted in the Office Action that the teaching of Kallgren is deficient because “it does not explicitly teach the use of the disclosed pack with a combination of a proton pump inhibitor (lansoprazole) and a non-steroidal anti-inflammatory drug (naproxen)” (page 3, paragraph 1 of the current Office Action).

The Office Action also cites Depui et al. as teaching “a drug combination comprising a proton pump inhibitor with a non-steroidal anti-inflammatory drug” in an effort to show prior teaching of the active ingredients claimed as part of the subject packaging system. However, Depui et al. strictly describe a single dosage form that contains both a proton pump inhibitor (e.g. lansoprazole) with a non-steroidal anti-inflammatory drug (e.g. naproxen). It is respectfully submitted that Depui et al do not teach or suggest providing the two claimed active ingredients in separate dosage forms in a blister package. In fact, Depui et al. state that the two actives, lansoprazole and naproxen, should not be provided separately. Specifically, the Depui et al. specification states: “Therefore, administration of two or even more different tablets to the patient is not convenient or satisfactory to achieve the most optimal results (col. 2, line 36-38).” Because Depui says administration of two tablets is not satisfactory, and does not achieve the desired results, applicant respectfully submits that the Depui reference teaches away from the subject invention, which provides in a blister pack, the two active drugs each in a separate dosage form. Therefore, because Depui teaches away, its combination with the other references would not render obvious the subject invention as now claimed.

Like the Kallgren reference, it is respectfully submitted that Eek fails to teach a packaging system which contains the specific actives of lansoprazole and naproxen. Accordingly, there is no teaching or suggestion in Eek for a packaging system containing in separate dosage forms, the active ingredients lansoprazole and naproxen as claimed in the subject application.

It is respectfully submitted that Kallgren, Depui et al., and Eek are improperly combined, and one of ordinary skill in the art would not be motivated to combine Kallgren, Depui et al. and Eek to arrive at the invention as recited in the present claims. In support of this position, as discussed above, Depui et al. is directed to two or more active substances in the same dosage form, in contrast to the Kallgren and Eek references which describe the drugs in separate unit dosage forms. Therefore, it is respectfully submitted that in the very least, there is no motivation to combine Depui et al. with the Kallgren or Eek references.

Further, each of the cited references have specific deficiencies which fail to teach or suggest the claimed invention as none of these references would direct a person of ordinary skill to the novel combination of lansoprazole and naproxen, in separate dosage forms, packaged in a blister pack. Any combination of the cited references relies on Depui to provide disclosure of the claimed active ingredients. However, Depui specifically teaches that separate dosage forms for the two actives is “not satisfactory” and thus would not provide an optimal result. Therefore, because Depui teaches away from the subject invention, applicant asserts the combination of Kallgren, Depui, and Eek teaches away from the subject invention and fail to render the subject invention obvious.

Applicant submits that by providing the separate actives in separate dosage forms in a blister pack, the claimed invention allows for flexibility in dosing regimens. This flexibility allows the administration times of each active to be separately individualized based on the needs of the patient. For example, the therapeutic combination of dosing lansoprazole and naproxen benefits from this flexibility because the onset of action for lansoprazole is delayed by several hours. In a dosing regimen whereby the patient is instructed to take the lansoprazole several hours before the naproxen, the lansoprazole has time to provide the therapeutic effect and can reduce or prevent gastric irritation commonly associated with naproxen. This advantage is not contemplated by the cited references.

Because the combination of the cited references leads to a packaging system containing a single dosage form, the only way to arrive at the claimed invention from the combined cited references would be to modify the result of the reference combination. But, there must be a teaching or suggestion in the prior art to make such a modification to the result of the combined references. Because Depui specifically teaches that administering two or even more different tablets to the patient is not convenient or satisfactory, applicant respectfully asserts that there is no motivation to modify the combination of references to arrive at the claimed invention. Applicant further asserts that the only way one to arrive at the currently claimed invention from the cited references, separately, combined, or modified, would be to engage in the impermissible use of hindsight reconstruction through the use of knowledge gleaned from applicant's disclosure. Hindsight reconstruction does not support an obviousness rejection under 35 USC 103(a).

As noted in Applicants previous response, the Examiners agreed during the interview conducted on March 24, 2004, that even assuming *arguendo* that Depui was properly combinable with Eek and Kallgren, the result would be two active agents in a single dosage form, contained in packaging material, rather than the packaging system of the present invention.

It is noted that the indicia limitation is not being relied upon and was not relied upon in any argument for the patentability of the present invention (see Statement of Substance of Interview dated March 26, 2004). Therefore, the Examiner's reliance on *In re Ngai* is unfounded.

Applicant asserts that providing lansoprazole and naproxen separately in a blister package is not taught or suggested in any of the cited references taken alone or in combination. Without a teaching or suggestion founded in the prior art, a rejection under 35 USC 103(a) cannot be properly applied. Applicant respectfully requests reconsideration and withdrawal of this rejection.

### III. CONCLUSION

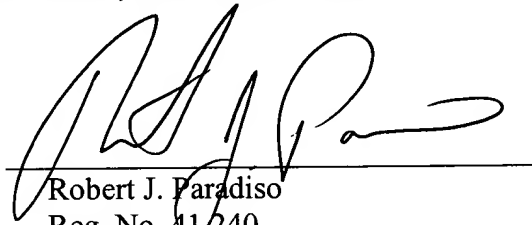
In view of the arguments presented, it is respectfully submitted that this application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at the telephone number provided below if he believes that a telephonic interview will advance the prosecution of this application.

Respectfully Submitted,

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